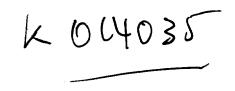
MAR 7 2002

CoolTouch Corporation CoolTouch Nd:YAG Laser System 510(k) Premarket Notification



510(k) SUMMARY

Submitter:

CoolTouch Corporation

Address:

9085 Foothills Boulevard Roseville, CA 95747

Contact Person:

Donald V. Johnson

Director of Regulatory and Quality Affairs

Telephone:

(916) 677-1900

Facsimile:

(916) 677-1901

Date Prepared:

December 6, 2001

Device Trade Name:

CoolTouch Nd:YAG Laser System CoolTouch-II Nd:YAG Laser System

Common Name:

Nd: YAG Pulsed Surgical Laser

Classification Name:

Laser Surgical Instrument. 21 C.F.R. § 878.4810

Legally Marketed Predicate Device:

New Star Lasers, Inc. Model 130 Nd:YAG Surgical

Laser System (K962791).

Description of the CoolTouch

Nd:YAG Laser Systems:

The CoolTouch Nd:YAG Laser Systems are ND:YAG lasers producing laser emission at 1320 nm. The lasers consist of three interconnected sections: The cabinet, which houses the power supply, cooling system, microcontroller and the laser, the fiber optics, and the

handpiece.

Intended use of CoolTouch Nd:YAG Laser Systems:

The CoolTouch Nd:YAG Laser Systems are indicated for the treatment of periorbital and perioral wrinkles.

Nonclinical Performance Data:

None

Clinical Performance Data:

Clinical trials produced results that indicate that that CoolTouch Nd:YAG Laser System is effective in the

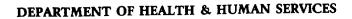
treatment of periorbital and perioral wrinkles.

Conclusion:

The CoolTouch Nd:YAG Laser Systems are indicated for the treatment of periorbital and perioral wrinkles.

Additional Information:

None requested at this time





Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

MAR 7 2002

Mr. Donald V. Johnson Director of Regulatory and Quality Affairs CoolTouch Corporation 9085 Foothills Boulevard Roseville, CA 95747

Re: K014035

Trade/Device Name: Cooltouch Nd:YAG Laser System

CoolTouch-II Nd:YAG Laser System

Regulation Number: 878.4810

Regulation Name: Laser surgical instrument for use in general and

plastic surgery and in dermatology

Regulatory Class: II Product Code: GEX Dated: December 6, 2001 Received: December 7, 2001

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost For Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and Neurological Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number:	150410		
Device Name: CoolTou Laser Systems	uch Corporation "CoolTo	ouch"and "CoolTouch-II" Nd:YA	<u>\G</u>
Indications for Use:			
The CoolTouch Nd:Y periorbital and perior	AG Laser Systems a al wrinkles.	re indicated for the treatme	nt of
(Please do not write	below this line - Continue or	n another page if needed)	
Concu	rrence of CDRH, Office of D	evice Evaluation (ODE)	_
Prescription Use (per 21 CFR 801.109)	OR	Over-the-Counter Use	

Myram C. Provest
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number <u>K0/4035</u>